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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,422	11/07/2006	Eggert Stockfleth	50125/084002	7550
<div>21559 7590 07/06/2007</div> <div>CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110</div>				
			EXAMINER	
			MI, QIUWEN	
			ART UNIT	PAPER NUMBER
			1655	
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			07/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,422	Applicant(s) STOCKFLETH, EGGERT	
	Examiner Qiuwen Mi	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER; FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 33, 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the following species in the reply filed on 5/29/2007 is acknowledged.

- (1) R1, R2, R5, R6, R7, and R8 are OH; R3 is H; and R4 and R9 are formula (III);
- (2) the additive isopropyl myristate;
- (3) the carrier ointment;
- (4) the anticancer treatment curettage;
- (5) the chemotherapy agent 5-fluorouracil;

Claims Pending

Claims 1-35 are pending. Claims 33 and 34 are withdrawn. Claims 1-32, and 35 are examined on the merits.

Claim Rejections –35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1, 3-5, and 8-20, and 27 are rejected under 35 USC § 102 (a) as being anticipated by Dou et al (US 2002/0151582).

Dou et al teach administering to the patient an effective amount of polyphenol compounds EGCG (formula I and II in claims 13 and 14), ECG, GCG, or CG from green tea with pharmaceutically acceptable carrier or excipient (additive) (p0043) for treating cancer such as melanoma of the skin (skin cancer) (p0009, claim 3).

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1-3, 6, 8-20, 27, 29, 30, and 35 are rejected under 35 USC § 102 (a) as being anticipated by Evans et al (US 2003/0143165).

Evans et al teach topical (see Title) (ointment) (p0074) treatment of UV light-induced skin cancer, precancerous lesions, and actinic keratosis (p0031) in mammals, such as humans, using green tea and a carrier medium (claim 9) (see Abstract, p0013). As evidenced by Dou et al (US 2002/0151582), green tea contains polyphenol compounds EGCG (formula I and II in claims 13 and 14), ECG, GCG, or CG (claim 3).

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1-6, 8-20, and 29 are rejected under 35 USC § 102 (b) as being anticipated by Zhao et al (Proceedings of the American Association for Cancer Research 39, 382, 1998).

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Zhao et al teach topically treating human volunteers with green tea extracts prior to UVB irradiation resulted in a dose-dependent protection against acute erythema formation. The green tea epicatechin includes EGCG (formula I and II in claims 13 and 14), ECG, EGC and EC

As evidenced by Katiyar et al (Arch Dermatol, 136: 989-994, 2000), erythema is often used as early markers of skin tumor promotion (page 990, right column, 4th paragraph).

Therefore, the reference is deemed to anticipate the instant claim above.

Claims 1, 3-5, 8-20, and 27-30 are rejected under 35 USC § 102 (b) as being anticipated by Hersh et al (US 6,337,320).

Hersh et al teach treating UV radiation-induced skin damage (see Abstract) such as skin cancer (col 1, lines 40-45) with topical compositions (such as an ointment) comprising green tea (claims 6 and 22) and isopropyl myristate (col 17, Example 7).

Therefore, the reference is deemed to anticipate the instant claim above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3-5, and 7-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dou et al (US 2002/0151582).

Dou et al teach administering to the patient an effective amount of polyphenol compounds EGCG (formula I and II in claims 13 and 14), ECG, GCG, or CG from green tea with pharmaceutically acceptable carrier or excipient (additive) (p0043) for treating cancer such as melanoma of the skin (skin cancer) (should include different stages, such as advanced stage) (p0009, claim 3).

Dou et al do not teach the amount of the polyphenols in the composition.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Dou et al since it yielded beneficial results in skin cancer treatment, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

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Claims 1-3, 6, 8-27, 29, 30, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US 2003/0143165).

Evans et al teach topical (see Title) (ointment) (p0074) treatment of UV light-induced skin cancer, precancerous lesions, and actinic keratosis (p0031) in mammals, such as humans, using green tea and a carrier medium (claim 9) (see Abstract, p0013). As evidenced by Dou et al (US 2002/0151582), green tea contains polyphenol compounds EGCG (formula I and II in claims 13 and 14), ECG, GCG, or CG (claim 3).

Evans et al do not teach the amount of the polyphenols in the composition.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Evans et al since it yielded beneficial results in skin cancer treatment, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1-6, 8-27, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhao et al (Proceedings of the American Association for Cancer Research 39, 382, 1998).

Zhao et al teach topically treating human volunteers with green tea extracts prior to UVB irradiation resulted in a dose-dependent protection against acute erythema formation. The green tea epicatechin includes EGCG (formula I and II in claims 13 and 14), ECG, EGC and EC

As evidenced by Katiyar et al (Arch Dermatol, 136: 989-994, 2000), erythema is often used as early markers of skin tumor promotion (page 990, right column, 4th paragraph).

Zhao et al do not teach the amount of the polyphenols in the composition.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Zhao et al since it provides scientific data for skin cancer treatment, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1, 3-5, 8-20, and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hersh et al (US 6,337,320).

Hersh et al teach treating UV radiation-induced skin damage (see Abstract) such as skin cancer (col 1, lines 40-45) with topical compositions (such as an ointment) comprising green tea (claims 6 and 22) and isopropyl myristate (col 17, Example 7).

Hersh et al do not teach the amount of the polyphenols in the composition.

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the inventions of Hersh et al since it yielded beneficial results in skin cancer treatment, one of ordinary skill in the art would have been motivated to make the modifications. The result-effective adjustment in conventional working parameters (e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

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Claims 1, 3-5, 7-27, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dou et al (US 2002/0151582) in view of Sheffield, SR (US 2002/0031535).

Claims 1, 3-5, and 7-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dou et al (US 2002/0151582).

Dou et al teach administering to the patient an effective amount of polyphenol compounds EGCG (formula I and II in claims 13 and 14), ECG, GCG, or CG from green tea with pharmaceutically acceptable carrier or excipient (additive) (p0043) for treating cancer such as melanoma of the skin (skin cancer) (should include different stages, such as advanced stage) (p0009, claim 3).

Dou et al do not teach other cancer treatment or the claimed amount of the polyphenols.

Sheffield, SR teaches that skin cancer may be removed by excisional surgery, curettage-electrodesiccation, cryosurgery, radiation therapy, topical chemotherapy (p0003).

Therefore, it would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the skin cancer therapy of Sheffield, SR in Dou et al since Sheffield, SR teach that it is well known that skin cancer may be removed by one of several methods including excisional surgery, curettage-electrodesiccation, cryosurgery, radiation therapy, topical chemotherapy, what is still needed is a topical formulation for removal of surface oriented skin cancer and other skin disorders (p0003). Since Sheffield, SR yielded beneficial results in skin cancer treatment, one of ordinary skill in the art would have been motivated to make the modifications and combine the curettage with a topical formulation to effectively treat skin cancer. The result-effective adjustment in conventional working parameters

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(e.g., determining an appropriate amount of the components within the composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MICHAEL MELLER
PRIMARY EXAMINER